



# CONTRACT DEVELOPMENT

PROCEDURE ID: YMP-LBNL-QIP-4.0

REV. 2, MOD. 0

EFFECTIVE: 6/2/97

## 1. PURPOSE

This quality implementing procedure (QIP) establishes methods to ensure that procurement documents include or reference the applicable quality assurance (QA) requirements, site investigation, or other management controls that are necessary to ensure adequate quality in scientific investigations of the Yucca Mountain Site Characterization Project at Ernest Orlando Lawrence Berkeley National Laboratory (YMP-LBNL).

## 2. SCOPE

This procedure applies to the development of all contracts for services, from non-LBNL sources and outside the YMP-LBNL-QIP-1.0 line of authority, to support YMP-LBNL quality affecting activities. This procedure does not apply to services such as administrative/clerical support; technical reviews or audits; transfer of property; or interface controls between YMP participant organizations. Contracts developed prior to the effective date of this revision shall require no remedial action. Since YMP-LBNL does not purchase quality-affecting items, as defined by the Quality Assurance Requirements Description (QARD), this procedure applies only to the purchase by YMP-LBNL of services. Note: YMP-LBNL purchases of calibration services for applicable equipment shall also satisfy the associated QA requirements of YMP-LBNL-QIP-12.0.

## 3. PROCEDURE

### 3.1 Requests

- 3.1.1 For requests for services, the Requester shall coordinate with the YMP-LBNL Engineering Assurance (EA) office to ensure all QA requirements have been considered in preparation of the Requisition Request (Attachment 1) and that the Requisition Request fulfills requirements in YMP-LBNL-QIP-4.1. These procurements must be planned and documented and must include appropriate technical and QA requirements and ensure a systematic approach to the procurement process. The requirements shall be included relative to the level of importance, complexity, and quantity of the service being requested and the supplier's quality performance.
- 3.1.2 When calibration is a requirement of the request, the Requester shall include the Attachment to Requisition Request for Calibration Services (Attachment 3) as part of the Requisition Request.

- 3.1.3 The Requester shall submit a completed Requisition Request (Attachment 1) to the Project Manager (PM) and shall ensure that information pertinent to the request is available for the review process. The PM or designee shall review the Requisition Request to ensure that technical requirements and budgetary and programmatic content are appropriate for the service being requested and approve it by signature (in Part H of Attachment 1).
- 3.1.4 A management review shall be done by personnel who have an understanding of the scope of the procurement.

### **3.2 YMP-LBNL EA Manager's Review of Request:**

The YMP-LBNL EA Manager or designee shall perform a management review of the request to determine if appropriate QA requirements are included and to determine if the supplier is listed in the Yucca Mountain Quality Assurance Office (OQA) Qualified Suppliers List (QSL) for the scope of work identified in the Requisition Request or if the supplier will work according to the YMP-LBNL QA program (in which case appropriate procedures shall be made available to the supplier) while being qualified (see Section 3.2.3.4).

- 3.2.1 If the EA Manager's review identifies no deficiencies in a request, the EA Manager shall approve and forward it to an Administrative Officer (AO) or the supplier purchasing agent.
- 3.2.2 If the EA Manager's review identifies deficiencies in a request, EA Manager shall return the request to the Requester for disposition or rework.
- 3.2.3 If the Requisition Request requires the use of a vendor not on the QSL, and the time needed for the normal supplier evaluation process for the supplier to be added to the QSL could result in an irrecoverable loss of data, the EA Manager shall notify the Requester to submit a justification for the emergency use of the supplier to the EA Office. After acceptance of the emergency justification, the completed request and accompanying documentation, such as justifications, shall be forwarded to an AO or the supplier purchasing agent. The Requisition Request will then proceed through the normal QA procurement process. In the meantime, the supplier shall perform work to YMP-LBNL QIPs and technical implementing procedures (TIPs) as required in the contract until they attain qualified status.
- 3.2.4. If a supplier is not qualified and will be working to its own QA program, the YMP-LBNL EA Manager (or designee) shall initiate the supplier evaluation in accordance with Section 3.7 The EA Manager shall assure that any deficiencies in the program are corrected by the supplier and accepted by the OQA, before allowing the supplier to start any work subject to (QARD) requirements.

### **3.3 Administrative Processing of Request:**

Upon receipt of the approved Requisition Request, an AO shall process a requisition according to LBNL administrative practices. The supplier shall adhere to YMP-LBNL QA procedures as the requisition proceeds according to the participant's purchasing practices.

### **3.4 LBNL Buyer Processing of Requisition:**

The LBNL Buyer will determine what type of contract the procurement document requires.

3.4.1 The LBNL buyer shall prepare the documentation in accordance with the Requisition Request and follow the procedures and standards of LBNL Purchasing Department and its QA program.

3.4.1.1 If the procurement is issued for bid/proposal the LBNL Buyer shall check supplier proposals upon receipt to assure that they satisfactorily meet all the requisition requirements and forward all satisfactory proposals to the Requester for evaluation. The Requester shall evaluate the proposals and return them with any comments to the LBNL Buyer. The LBNL Buyer shall then conduct the negotiations with the perspective suppliers to resolve any unacceptable conditions (quality or other) and, in turn, select the final supplier. When a proposal meeting all of the requested requirements is selected by the LBNL Buyer, the LBNL Buyer shall forward the procurement document to the Requester.

3.4.1.2 The Requester shall review the document to ensure that it includes the provisions identified in the Requisition Request. The Requester shall complete the Requester Review section of the Final Procurement Review form and forward it, with a copy of the final proposal, to the EA Manager.

3.4.1.3 The EA Manager shall review the document to ensure that the final procurement document includes provisions to ensure that the services will meet specified requirements. The EA Manager shall complete the Engineering Assurance Review section of the Final Procurement Review form and forward it with a copy of the final procurement document to the OQA Representative for concurrence.

3.4.1.4 The OQA representative shall perform a QA review of the procurement document and complete the Final Procurement

Review form (Attachment 2) to determine whether the requirements in Attachment 4 and QIP 4.1 have been met, and whether any changes or corrections are necessary before the final procurement document is issued to the supplier.

3.4.1.3.1 If the OQA representative determines that the procurement document does not include the appropriate QA requirements, the OQA representative shall forward the documentation to the EA Manager for resolution.

3.4.1.3.2 If the OQA representative determines that the procurement document includes the appropriate QA requirements, the OQA representative shall sign the Final Procurement Review form and forward the form and associated documentation to the EA Manager for PM's approval.

3.4.1.3.3 If source verification is to be performed, the OQA representative shall ensure a source verification plan is developed in accordance with the applicable OCRWM procedure, and that the source verification is scheduled.

3.4.1.4 Upon approval, the PM shall forward the documents to an AO for processing in accordance with LBNL practices.

3.4.1.5 The AO shall forward all forms and related documents to the requester for inclusion in the procurement records package to be submitted to the YMP-LBNL Record Processing Center. The AO shall notify the LBNL Buyer to proceed.

### **3.5 Purchases by Suppliers:**

Suppliers performing quality-affecting activities for the YMP based on a management agreement or similar document shall incorporate the appropriate QA requirements into any sub-tier supplier document issued. The supplier shall submit the final procurement documents to the YMP-LBNL EA Manager for approval and to obtain the OQA representative's signature for concurrence before the final procurement documents are released to a sub-tier supplier.

### **3.6 Modifications:**

All modifications and changes to procurement documents, except modifications exercising the option to renew a contract for an additional year,

staffing changes, or increasing or decreasing funds, shall be subject to the same degree of control and review as used in the preparation of the original documents.

3.6.1 Changes made as a result of proposal/bid evaluations or pre-contract negotiations shall be incorporated into the procurement documents by the LBNL Buyer. The evaluation of these changes and the resulting impact shall be completed by the Requester and approved by the EA Manager before the contract is awarded. This evaluation shall consider:

- appropriate requirements as specified in this section (changes to QA requirements are to be reviewed by the OQA representative to confirm that appropriate QA requirements are included),
- analysis of exceptions or changes requested or specified by the supplier and a determination of the impact such changes have on the intent of the procurement documents or quality of the service to be furnished,
- personnel qualification for staffing changes.

### **3.7 Supplier Evaluation**

3.7.1 If a supplier will be working to its own QA Program and is not qualified or not qualified for the identified scope of work, the EA Manager shall initiate the YMP-LBNL technical evaluation of the proposed supplier.

3.7.1.1 Evaluations shall be done by personnel, selected by the PM and EA Manager, who have an understanding of the requirements of the procurement.

3.7.1.2 Evaluations of suppliers shall include an examination of one or more of the following:

- Supplier's history for providing similar services;
- Supplier's current QA records and supporting qualitative and quantitative information; and/or
- Supplier's technical and quality capability based on facilities, personnel, and QA program implementation.

3.7.1.3 The evaluation shall include, as appropriate, the following consistent with the importance, complexity, and quantity of services being procured:

- Technical considerations
- Statement of Work specifications
- Quality assurance program requirements
- Supplier personnel

- Supplier production capability
- Alternatives
- Exceptions
- Technical evaluation criteria
- Acceptance criteria

3.7.1.4 The evaluations shall be documented by the reviewer(s) and forwarded to the EA Manager for evaluation and inclusion in the project files.

3.7.2 If YMP-LBNL elects to proceed with the qualification of the proposed supplier based on the results of the YMP-LBNL evaluation, the EA Manager shall notify the OQA Representative to evaluate the proposed supplier's QA program in accordance with AP-7.4Q.

#### **4. RECORDS MANAGEMENT**

##### **4.1 Lifetime**

Requisition Request

Requisition

Modification and change documents

Acceptance of changes to procurement documents

Final Procurement Review form

Final proposal

Final procurement documents (including the final proposal)

Any other relevant information

##### **4.2 Non-permanent**

None

##### **4.3 Controlled Documents**

None

##### **4.4 Records Center Documents**

Records associated with this procedure shall be submitted to the YMP-LBNL Local Records Processing Center, in accordance with YMP-LBNL-QIP-17.0 and AP-17.1Q.

#### **5. RESPONSIBILITIES**

**5.1 The YMP-LBNL Project Manager (PM)** or designee is responsible for ensuring that purchases of quality-affecting services are processed in accordance with the requirements of this procedure, that applicable technical and QA requirements are included in the Requisition Request, and for approving Requisition Requests (Attachment 1).

- 5.2 The YMP-LBNL Engineering Assurance (EA) Manager or designee is responsible for the review of all final procurement documents initiated per this procedure.
- 5.3 The Office of Quality Assurance (OQA) representative is responsible for reviewing all procurements for inclusion of the applicable QARD requirements.
- 5.4 The Requester of a procurement is responsible for initiating requests for quality-affecting services in accordance with this procedure; including all necessary information in a Requisition Request (Attachment 1); reviewing and approving any technical changes to a final procurement document that differ from the original request; and completing the Final Procurement Review form (Attachment 2), as applicable.
- 5.5 The Administrative Officer (AO) is responsible for completing requisitions according to the information provided in the approved Requisition Request; submitting the requisitions to the servicing LBNL Buyer; and providing all associated records to the requester for submittal to the YMP-LBNL Records Processing Center.
- 5.6 LBNL Purchasing Department Buyers are responsible for preparing final procurement documents; providing copies of proposals to the Requester for evaluation; negotiating contracts; issuing final approved procurement documents; and distributing copies of procurement documents.
- 5.7 Suppliers are responsible for submitting purchase requests and final procurement documents of quality-affecting purchases to the YMP-LBNL QA Manager for approval prior to release to a supplier/sub-contractor; for procuring from YMP-LBNL approved suppliers only; and for submitting records packages of quality-affecting purchases the YMP-LBNL purchaser.

## 6. ACRONYMS AND DEFINITIONS

### 6.1 Acronyms

AO	Administrative Officer
QSL	Qualified Supplier List, maintained by the Yucca Mountain Site Characterization Project Office
OQA	Office of Quality Assurance

### 6.2 Definitions

**Final Procurement Document:** A purchase order or contract, including any applicable modifications.

**Final Proposal:** A proposal that is acceptable to the Requester and is a supplier's best and final offer, that will have no further changes, and will become the contract.

**Management Review:** For the purposes of this procedure, a management review of a document is a review performed by the PM, EA Manager, or appropriate PI, to a level of detail determined by the reviewer. A management review may range in rigor from a simple undocumented completeness check to a fully documented review per the requirements of YMP-LBNL-QIP-6.1.

**Supplier:** A person or group of persons providing support to YMP-LBNL in quality-affecting activities. A supplier may be a person or organization providing support through agreement or a similar document.

## 7. REFERENCES

- AP-17.1Q, Record Source responsibilities for Inclusionary Records.
- DOE/RW-0333P, Quality Assurance Requirements and Description
- QAP 1.1, Organization
- YMP-LBNL-QIP-1.0, YMP-LBNL Organizational Structure
- YMP-LBNL-QIP-4.1, QA Contract Content
- YMP-LBNL-QIP-6.1, Document Review
- YMP-LBNL-QIP-12.0, Documenting the Usage of Measuring and Test Equipment
- YMP-LBNL-QIP-17.0, Submitting Records to the YMP-LBNL Records Center

## 8. ATTACHMENTS

Attachment 1: Requisition Request

Attachment 2: Final Procurement Review

Attachment 3: Attachment to Requisition Request for Calibration Services

Attachment 4: Supplier Performance Evaluation

## 9. REVISION HISTORY

9/22/95 - Revision 0, Modification 1:

Clarified listing of lifetime records generated by this procedure.

10/21/96 - Revision 1, Modification 0:

Revised procedure to reflect requirements changes in QARD, Rev. 5.

Made general clarifications and improvements.

6/2/97 -Revision 2, Modification 0:

Revised procedure to introduce the term Engineering Assurance (EA) and to identify the role and responsibilities of the EA Manager and OQA representative.

## 10. APPROVALS

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Preparer:

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Date

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Technical Reviewer:

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Date

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Technical Reviewer:

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Date

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QA Reviewer:

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Date

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QA Manager:

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Date

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Project Manager:

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Date

REQUISITION REQUEST

*This form is to be completed by the Requester. If the purchase involves special requirements other than those listed on this requisition request, additional pages may be attached. when Part I is completed and signed by the Requester, the Requester shall obtain an approval signature of the Project Manager and forward the form to the Engineering Assurance Manager.*

*The Requester shall circle options and fill in blanks as necessary. If a topic does not apply, the Requester shall indicate by circling "Not Applicable" or using "N/A."*

PART I – IDENTIFICATION:

A. DATE: _____	ACCT. TO BE CHARGED: _____
PROJECT: _____	WBS NO: _____
REQUESTER'S PHONE NO.: _____	SCP NO: _____
REQUISITION: _____	DATE REQUIRED: _____
DELIVER TO: _____	SUGGESTED SUPPLIER/VENDOR: (If sole source, attach justification)
_____	IS SUPPLIER ON THE QSL? <input type="checkbox"/> Yes <input type="checkbox"/> No
_____	_____
_____	_____
_____	_____
_____	_____

B. STATEMENT OF SCOPE OF WORK TO BE PERFORMED BY SUPPLIER:

Describe the service. Include quantities and estimated cost where appropriate.

_____
_____
_____
_____
_____

**REQUISITION REQUEST (Continued)****C. TECHNICAL REQUIREMENTS** (circle and complete appropriate sections below):

1. Specific documents (such as technical procedures, instructions, codes, or standards) that describe the technical requirements of the services to be furnished shall be specified. The revision level or change status of these documents shall also be identified. Include such requirements as hold and witness points beyond which work cannot proceed without YMP-LBNL authorization.

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2. Tests, inspection, and acceptance requirements:

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3. Not applicable.

**D. QUALITY ASSURANCE PROGRAM REQUIREMENTS** (circle and complete appropriate sections below):

1. The supplier shall have a Quality Assurance (QA) program that implements the requirements of the Quality Assurance Requirements and Description (QARD) prior to the initiation of work. If the supplier does not have an approved program, the work done in support of this procurement shall be performed in accordance with the YMP-LBNL QA Program. If the supplier is not working to the entire YMP-LBNL QA Program, identify YMP-LBNL QA implementing documents (e.g., QIPs, include Revision number) below that are applicable to the supplier. All applicable implementing documents shall be provided to the supplier.

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2. Work done in support of this procurement shall be performed in accordance with the QA Program of the supplier that implements applicable YMP-LBNL QA requirements as approved by YMP-LBNL. The extent of the QA Program shall depend on the scope, nature, or complexity of the service being procured.

**REQUISITION REQUEST (Continued)****E. DOCUMENTATION REQUIRED FROM SUPPLIER:** (Any documentation to be provided to the YMP-LBNL for information, review, or acceptance.)

1. Calibration: When calibration documentation is required, the requirements of YMP-LBNL-QIP-12.0 shall be met. Requester shall include a copy of Attachment 3 (Attachment to Requisition Request for Calibration Services) with the Requisition Request. If the Requester has other calibration requirements, Requester shall add them to bottom section of Attachment 3.
2. Other: \_\_\_\_\_
3. Documentation submittal schedule: (Identify when the documentation is required.)  
\_\_\_\_\_
4. No documentation from supplier required.

**F. DOCUMENTATION MAINTAINED BY SUPPLIER:** (Any documentation pertinent to this procurement the Requester deems necessary for the supplier to maintain as QA records. Identify retention times and disposition requirements.)

- 1.
2. Not applicable.

**G. SUPPLIER NONCONFORMANCES:**

1. If the supplier identifies a condition which might preclude acceptable performance of this procurement, the supplier shall notify the LBNL Buyer in writing. The notification will include a proposed resolution and justification. Examples of possible deficiencies include contamination of samples, damage to instruments, etc. The LBNL Buyer shall transmit the notification to the Requester and Engineering Assurance Manager.

The YMP-LBNL Engineering Assurance Manager and the Requester shall review the supplier's proposed resolution. Resolutions require OQA concurrence and verification. When there exists a possibility that the final procurement document may be affected by the acceptable resolution, the YMP-LBNL Engineering Assurance Manager shall coordinate with the LBNL Buyer. The OQA and, as needed, the Requester will verify the resolution of the deficiency.

2. Not applicable.

**H. SIGNATURES:**

REQUESTED: \_\_\_\_\_

Printed Name (Requester)	Title	Signature	Date
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APPROVED: \_\_\_\_\_

Printed Name (Project Manager)	Signature	Date
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**REQUISITION REQUEST (Continued)**

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**PART II – SUPPLIER QUALIFICATION REVIEW BY EA**

1. Supplier has been approved. QSL ID: \_\_\_\_\_  
(Fill in QSL identification)
2. Not Applicable.
3. Supplier selection and/or evaluation is required before approval of final procurement document.

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Printed Name (EA Manager)

Signature

Date

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**PART III – LBNL BUYER:**

All quality-affecting purchases must be reviewed and approved by the OQA representative or designee, prior to release of final procurement document to the vendor/supplier/contractor.

Include the following clauses in the final procurement document:

1. YMP-LBNL verification activities shall not relieve the supplier of responsibility for verification of quality achievement.
  2. The supplier's records and facilities related to the specific procurement/contract shall be accessible to YMP-LBNL, DOE personnel or their representatives for purchaser inspection and /or audit.
  3. Supplier shall incorporate appropriate QARD requirements into any sub-tier supplier-issue procurement document; therefore, supplier shall not sub-contract any part of this procurement without first consulting with YMP-LBNL.
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## FINAL PROCUREMENT REVIEW

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### PART I – IDENTIFICATION:

PROCUREMENT DOCUMENT: \_\_\_\_\_

SUPPLIER: \_\_\_\_\_

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### PART II – REQUESTER REVIEW:

The final procurement document includes provisions to ensure that the services will meet specified requirements.

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Printed Name (Requester)	Title	Signature	Date
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### PART III – ENGINEERING ASSURANCE REVIEW:

The final procurement document includes provisions to ensure that the services will meet specified requirements.

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Printed Name (EA Manager)	Signature	Date
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### PART IV – QUALITY ASSURANCE REVIEW: [Check appropriate block(s)]

The final proposal meets QA requirements.

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Printed Name (OQA Representative)	Signature	Date
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### PART IV - PROJECT MANAGER APPROVAL

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Printed Name (Project Manager)	Signature	Date
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## **ATTACHMENT TO REQUISITION REQUEST FOR CALIBRATION SERVICES**

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*Instructions for Requester: For procurements requiring calibration, please add any requirements applicable to this request which are not listed below (see QSL).*

*Instructions for LBNL Buyer: Include the following in the Purchase Requisition*

The Requester or designee shall be notified immediately when a calibration instrument used to calibrate and certify YMP-LBNL equipment under this purchase order is found to be defective, out of calibration, or not certified as calibrated.

The following information shall be provided to the LBNL technical contact for each calibration performed:

1. Identification of the supplier.
2. Identification of equipment being calibrated (such as manufacturer, type, model, serial number, or other unique identifier).
3. Identification of calibration standard (such as manufacturer, type, model, serial number, or other unique identifier) and standard's range and accuracy, NIST traceability or similar information when using other recognized standards, and calibration procedure or method used. Alternatively, it is acceptable for calibration documentation to provide a reference to documentation containing the standard's identity, range, accuracy, traceability, and the procedure or method used.
4. Date of calibration
5. Records of actual calibration data values, when applicable, both before and after any adjustments, enabling the determination of whether the equipment was, and is, within required tolerance or accuracy. If adjustments are not performed, a second set of data is not required.
6. Identification of person performing the calibration.

The supplier of calibration services shall submit the above information to YMP-LBNL with the calibrated equipment.

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## SUPPLIER PERFORMANCE EVALUATION

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1. YMP-LBNL shall establish measures to interface with the supplier and to verify supplier's performance. **The extent of measures to be used in YMP-LBNL verification shall be a function of the relative importance, complexity, and quantity of services being procured, and the supplier's quality performance.** These measures shall include:
    - a. Establishing an understanding between YMP-LBNL and supplier of the requirements and specifications identified in the procurement documents.
    - b. Requiring supplier to identify planning procedures to be used in fulfilling procurement QA requirements.
    - c. Reviewing and receiving supplier documents (including QA documents) that are prepared or processed during work performed to fulfill QA and procurement document requirements. Measures shall be established for the acquisition, processing, and recorded evaluation of technical, inspection, and test data consistent with the acceptance criteria for the final product.
    - d. Identifying and processing necessary change information.
    - e. Establishing the method to be used to document information exchanges between YMP-LBNL and supplier.
    - f. Establishing the extent of source surveillance and inspection.
  2. The verification measures selected from the above shall be conducted as early as practical once the service is initiated. Any verification measure conducted by the YMP-LBNL shall not relieve the supplier of the responsibility for the verification of quality achievement. Evaluation of documentation to aid in the determination of the effectiveness of the supplier's quality assurance program shall be part of the verification.
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